Procedures (Volume I), under the Export & Import Policy, 2002—2007. While DEPB rates have been fixed for many items, there are also a large number for which no DEPB rates have been fixed. Blended socks fall in the latter category.

DEPB Scheme is only one of the duty neutralisation schemes available to exporters. Non-fixation of DEPB rates does not necessarily affect exporters adversely, as exporters have the option of availing benefits under other duty neutralization schemes under the EXIM Policy, as also the Duty Drawback Scheme implemented by Department of Revenue, Ministry of Finance.

The proposals for fixation of DEPB Rates are required to be routed through the respective Export Promotion Councils. Complete proposals for fixation of such rates are considered on merits, in the Directorate General of Foreign Trade, in consultation with the concerned Administrative Ministries including Department of Revenue.

Export Promotion Councils have been set up to promote and develop exports from the country. These EPCs are managed by elected bodies chosen by exporter members of the Councils.

Phase-I clinical trial of new drugs

*92. DR. VIJAY MALLYA :
SHRI LAJPAT RAI :

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are considering a proposal to reverse their earlier stand on the issue of Phase-I clinical trials of new drugs of foreign origin on Indian patients;

(b) whether the proposal is being considered to take advantage of getting access to the latest drugs and therapies in the world developed by foreign MNCs;

(c) whether Government have adopted a policy in this regard; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) to (d) Earlier as per Schedule Y of Drugs and

Cosmetics Rules, 1945, for new drug substances discovered in other countries, Phase-I trials were not usually allowed to be initiated in India unless Phase-I data from other countries were available. However, such trials were permitted even in the absence of Phase-I data from other countries if the drug is of special relevance to the health problem of India.

In order to update the requirements of pre-clinical and clinical study norms under Schedule Y at par with international norms and keeping in view the potential, which the country possesses in the field of clinical research, the Drug Technical Advisory Board (DTAB) agreed to undertake the review of Schedule Y. An extensive exercise has been undertaken in consultation with various experts in the field, including ICMR. A draft Notification GSR 694(E) has been published on 28th August, 2003 to invite comments/suggestions from stake holders.

For new drug substances discovered in India, clinical trials may be carried out in India from Phase I through Phase III and data should be submitted as required under item 5, 6 and 7 respectively of Appendix-I.

The Draft Notification provides that — "For new drugs substances discovered in countries other than India, Phase I data required under item 5 of Appendix I, from other country(ies) should be submitted along with the application. After Phase I data generated outside India has been submitted to the Licensing Authority, permission may be granted to repeat Phase I and to conduct Phase I and subsequently Phase III trials concurrently with other global trials for that drug. In all cases Phase III trials must be conducted in India before permission to market the drug in India is granted".

Service negotiations with WTO

*93. SHRIMATI BIMBA RAIKAR : Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether India has drawn up an initial offers list for the on-going service negotiations with the WTO;

(b) the areas where offers are being made by India; and

(c) the modes of supply for such services?